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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/416,735	10/13/1999	ISABELLA A. ATENCIO	CJ-0897Q	6563
7590	03/25/2004		EXAMINER	
RICHARD B MURPHY CANJI INC 3525 JOHN HOPKINS COURT SAN DIEGO, CA 92121			FALK, ANNE MARIE	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/416,735	ATENCIO ET AL.
<b>Examiner</b>	<b>Art Unit</b>	
Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 02 February 2004.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 5-7, 21-31 and 33-36 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 5-7, 21-31 and 33-36 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 02 February 2004 is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: *Notice to Comply.*

## DETAILED ACTION

The drawings filed February 2, 2004 have been entered.

The amendment filed May 9, 2003 has been entered. Claims 5 and 33 have been amended.

Although page 2 of the amendment requests cancellation of Claim 32, Claim 32 appears in the clean copy of the claims (page 5 of the amendment filed May 9, 2003).

Claims 5-7 and 21-35 appear as pending in Applicants' clean copy of the claims.

Claims 5-7, 21-31, and 33-36 are treated as pending (see explanation below).

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 9, 2003 has been entered.

### *Sequence Rules*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

**Sequences are disclosed in the specification and/or figures. The sequences are not identified by a sequence identifier (i.e., SEQ ID NO:) and no Sequence Listing has been submitted. For example, at page 29, line 7, and pages 42-44 a number of nucleotide sequences are disclosed. Applicant is reminded that the entire specification and figures should be reviewed for sequence disclosures and that each sequence disclosed in the specification must be identified by its sequence identifier (i.e., SEQ ID NO:). The specification must be amended to identify all disclosed sequences by their sequence identifier (i.e., SEQ ID NO), in accordance with 37 CFR 1.821(d).**

Applicant is given the same shortened statutory period set forth for response to this Office Action within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126, which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

In the amendment submitted May 9, 2003 the clean copy of the claims (page 6) is inconsistent with the marked up copy of the claims (page 5). At the time the amendment was submitted the amendment practice was such that the clean copy of the claims is the official version. However, in the

clean copy of the claims Applicants have renumbered the claims following cancelled Claim 32 as Claims 32-35. The claims currently listed as Claims 32-35 should be renumbered as Claims 33-36, respectively.

Applicant is required to submit a complete listing of the claims in accordance with 37 CFR 1.121 in the next response to correct the error.

The claims presented as Claims 32-35 are treated herein using their original and proper claim numbering which is 33-36, respectively. Claim 32, as-filed in the amendment of 6/19/01, is treated as cancelled.

#### *Specification*

The disclosure is objected to because of the following informalities:

On page 20, line 29, there is a blank space following the word “Example.”

Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7, 21-31, and 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-7, 21-31, and 33-36 are indefinite in their recitation of “wherein said method is practiced *in vitro* or *ex vivo*” because it is unclear what the distinction is between *in vitro* and *ex vivo* in the context of the claimed method.

Claim 22 is indefinite in its recitation of “wherein said replication deficient adenoviral vector encodes a therapeutic transgene” because a vector does not **encode** a transgene, although it can comprise

a transgene. Use of the claim language “wherein said replication deficient adenoviral vector **comprises** a therapeutic transgene” is recommended.

Claims 22-27 are indefinite in their recitation of “therapeutic transgene” because the specification defines a “therapeutic transgene” as a nucleotide sequence, the expression of which in the target cell produces a therapeutic effect (page 23, lines 26-27), but the claims are now limited to practicing the method *in vitro*. Since a therapeutic effect would be rendered to an organism, not a cell culture, a transgene cannot have a therapeutic effect *in vitro*. Thus, the metes and bounds of the claim are not clearly set forth.

Claim 35 is indefinite because it depends from Claim 32 which has been cancelled.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in—

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 5-7, 21-31, and 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Claudio et al. (1996, Experimental Cell Research 224(1): 63-71).

The claims are directed to a method for increasing the infectivity of a cell to a viral vector by treatment of the cell with a micro-calpain inhibitor. Although a variety of viral vectors are mentioned in the claims, the claimed method does not include contacting the cell with a viral vector.

Claudio et al. (1996) disclose contacting a murine fibrosarcoma cell line with calpain inhibitor I.

The abstract states that “[t]he activation of NF- $\kappa$ B can be blocked by the cysteine protease inhibitor calpain inhibitor I.” The effect of increasing the infectivity of a cell to a viral vector is an inherent property of the inhibitor and an inherent result of the contacting step.

Thus, the claimed invention is disclosed in the prior art.

Claim 5-7, 21-31, and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,015,787 (Potter et al.).

The claims are directed to a method for increasing the infectivity of a cell to a viral vector by treatment of the cell with a micro-calpain inhibitor. Although a variety of viral vectors are mentioned in the claims, the claimed method does not include contacting the cell with a viral vector.

Potter et al. disclose contacting cells with calpastat, an inhibitor of calpain. See e.g. Example 5. The reference discloses that calpastat is a fusion protein that contains a calpastatin peptide and a signal sequence capable of delivering the fusion protein into a cell. The effect of increasing the infectivity of a cell to a viral vector is considered an inherent property of the inhibitor and an inherent result of the contacting step.

Thus, the claimed invention is disclosed in the prior art.

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to William Phillips, whose telephone number is (571) 272-0548.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER